

K073620

## 510(K) SUMMARY

### **1. SUBMITTER:**

Zerusa Limited  
219-220 Business Innovation Centre, NUIG  
Galway, Ireland  
Telephone: 011-353-91-861611  
Establishment Registration Number: 3005395947

REL 27

Official contact: Mr. Ger Brett, CEO  
Phone: 011-353-91-863061  
Date Prepared: December 21, 2007

### **2. DEVICE:**

Tradename: Guardian™ Hemostasis Valve  
Classification Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold or Fitting  
Classification: Class II  
Common Name: Hemostatic Valve  
Product Code: 74 DTL  
Regulation Number: 870.4290

### **3. PREDICATE DEVICE:**

This current 510(k) Premarket Notification is being submitted for the addition of a Guidewire Torquer. The predicate device used to determine substantial equivalence for this device was the Zerusa Limited's currently marketed Guardian Hemostasis Valve (#K052381).

### **4. DEVICE DESCRIPTION:**

The Zerusa Guardian™ Hemostasis Valve is designed to be used as a conduit for which interventional devices with diameters up to 8.0F are inserted into the human vascular system.

The device has two seals: the low-pressure seal and the high-pressure seal. Depressing the cap engages the Quikloc™ to open the low-pressure seal, depressing the cap again closes the seal. The high-pressure seal is operated by rotating the nut clockwise.

Closure of the high-pressure seal secures the diagnostic/interventional device in position within the vasculature and also allows for pressure injections. The two independently operated seals allow for minimal blood loss during vascular procedures. When the low pressure seal is open, it allows the device to be flushed. During the procedure, the low pressure seal is opened in order to allow the advancement/withdrawal of diagnostic/interventional devices.

Included with the Guardian™ Hemostasis Valve is a Guidewire Introducer, which is used to facilitate entry of the guidewire into the hemostasis valve. The Guidewire Introducer has an effective length of 125mm (4.9") and an inside diameter of 0.6mm (or 0.023").

A Guidewire Torquer, intended to manipulate the steering of the guidewire within the vascular regions, is also included.

## **5. INTENDED USE:**

The Guardian Hemostasis Valve is intended to maintain hemostasis during the introduction, withdrawal and use of diagnostic/interventional devices during vascular procedures.

## **6. INDICATIONS FOR USE:**

The Guardian HV is intended to maintain hemostasis during the use of diagnostic/interventional devices. The device is indicated for maintaining a seal around diagnostic/interventional devices with outside diameters up to 8.0F (2.67 mm or 0.105") during diagnostic/interventional procedures.

The guidewire introducer is included to facilitate the guidewire's passage through the Guardian HV.

The Torque Device is intended to manipulate the steering of the guidewire within the vascular regions.

## **7. COMPARISON OF CHARACTERISTICS:**

Comparisons of the proposed and predicate devices show that the technological characteristics such as materials, performance characteristics, sterilization and packaging are identical or substantially equivalent to the currently marketed predicate devices.

## **8. PERFORMANCE DATA:**

The Guardian™ Hemostasis Valve was subjected to a full battery of performance testing. The results of the performance testing demonstrated the safety and effectiveness of the device.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 27 2008

Zerusa Limited  
c/o Mr. Gerard Brett  
CEO and Official Correspondent  
219-220 Business Innovation Centre, NUIG  
Galway, Ireland

Re: K073620  
Guardian™ Hemostasis Valve  
Regulation Number: 21 CFR 870.4290  
Regulation Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting  
Regulatory Class: Class II (two)  
Product Code: DTL  
Dated: December 21, 2007  
Received: December 26, 2007

Dear Mr. Brett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K073620

Device Name: Guardian™ Hemostasis Valve

Indications for Use: The Guardian HV is intended to maintain hemostasis during the use of diagnostic/interventional devices. The device is indicated for maintaining a seal around diagnostic/interventional devices with outside diameters up to 8.0F (2.67 mm or 0.105") during diagnostic/interventional procedures.

The guidewire introducer is included to facilitate the guidewire's passage through the Guardian HV.

The Torque device is included to manipulate the steering of the guidewire within the vascular regions.

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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

*(Posted July 1, 1998)*

B. Hammill  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K073620